

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/599,203	<b>Applicant(s)</b> YAMAZAKI ET AL.	
	<b>Examiner</b> ANNA PAGONAKIS	<b>Art Unit</b> 1628	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 05 January 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 11-14, 17 and 19.  
 Claim(s) withdrawn from consideration: 1-10, 15 and 18.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☒ Other: Interview Summary.

/Anna Pagonakis/  
 Examiner, Art Unit 1628

/Brandon J Fetterolf/  
 Primary Examiner, Art Unit 1642

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's remarks presented in the after-final amendment regarding the 103 rejection has been considered and entered into the record, but are not persuasive.

With regard to Applicant's traversal of the 103 rejection, Applicant alleges that Broten does not teach or suggest the effect of ENID-3213 on frequency or urinary incontinence. The compound ENID-3213 is not currently under examination and has not addressed in the rejection. Applicant states that Broton, also, teaches alpha1A-adrenoceptor antagonists may inhibit prostatic urethral contraction. Further, Applicant alleges that treatment of frequency or urinary incontinence has been done with anticholinergics, antispasmodics and beta3 adrenoreceptors agonists which target the smooth muscle of the bladder whereas silodosin has been, allegedly, known to inhibit the contraction of the muscle.

Applicant appears to be of the persuasion that, because Broten et al., disclose the inhibition of prostatic urethral contraction and further because silodosin was known to inhibit the contraction of the bladder, this somehow constitutes a teaching away from the instantly claimed compound. This is not persuasive. A preferred or exemplified embodiment does not constitute a teaching away from other embodiments disclosed within the four corners of the references, including non-preferred embodiments. Applicant is reminded that the disclosure of a reference must be considered as expansively as is reasonably possible to determine the full scope of the disclosure and, as a result, is most certainly not limited to that which is preferred and/or exemplified. Accordingly, Applicant's alleged teachings of Nishimatsu et al. are not persuasive. Again, Applicant's attention is drawn to Broten et al. which, specifically, teaches that KMD-3213, alternatively named silodosin, is known for the treatment of lower urinary tract symptoms which include increased urine flow rate, decreased residual urine volume and improving overall obstructive and irritative symptoms in patients with benign prostatic hyperplasia or symptomatic prostatism. The references cited by Applicant have been considered and do not teach away from treatment of lower urinary tract symptoms.

Applicant's point to the micturition interval measurement as shown in Example 2 of the present specification which used the acetic acid-stimulated frequency model is support of unexpected results. Though Applicant's results have been noted, they are not commensurate in scope with the present claims. Specifically, silodosin was utilized at an amount of 0.3 mg/kg and the elected compound was administered at 1 mg/kg.

The rejections are maintained for the reasons set forth above and those made previously of record.